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10/642,395	08/14/2003	Michael S.H. Chu	MIY-P01-024	9490

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EXAMINER	
POUS, NATALIE R	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,395	CHU ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/17/06, 3/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS: 11/22/04* .

DETAILED ACTION

Response to Arguments/Remarks

Regarding the Giesy reference

Applicant's arguments filed 6/7/06 have been fully considered but they are not persuasive. Applicant argues that the actuating mechanism of Giesy does not deliver the implant. Examiner respectfully disagrees. It is noted that the language of claims 1 and 10 recite "a pushing mechanism operatively interconnected with the handle *for* actuating the pusher tube...," as such actuating the pusher tube distally along a portion of the shaft to deliver the implant to the anatomical site is functional language, and examiner asserts that the device of Giesy is capable of performing that task. As the pusher tube is pushed over the junction as in figure 4 to lock the device in place, the tube may be retracted as seen in figure 3 to deploy the device. As such, examiner sustains the previous 35 USC 102(b) and 103(a) rejections of claims 1-19 under Giesy.

Regarding the Browning reference

Applicant's arguments, see page 9, filed 6/7/06, with respect to the rejection(s) of claim(s) 10 and 19 under Browning have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bonutti (US 5814072).

Regarding the combination of Browning and Makower

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be

established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Browning teaches a device for treating urinary incontinence that relies on the integrity of the structure of guide tube in combination with body tissue to deploy the guide tube from the shaft. Makower teaches an implant delivery device wherein it is not necessary to solely rely on the implant acting on friction with body tissue to be released from the shaft, but a pusher tube is present in order to effectively eject the implant from the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Browning with a pusher tube mechanism as taught by Makower in order to ensure that the guide tube is effectively ejected from the shaft.

Applicant further asserts that independent claims 25 and 32 distinguish over Browning in view of Makower. Applicant discusses amended claim 25, however amendments to the claims submitted 5/26/06 comprises original claim 25, see page 5 of the claims. Examiner respectfully disagrees with applicants position and asserts that the combination of Browning and Makower does teach the limitation of sliding the first guide tube off the shaft to deliver a first portion of the sling into the body of the patient. The reference to figure 8 was intended to draw applicants attention the separation of the guide tube and the shaft, and the

action of figure 8 in combination with the pusher mechanism of Makower as described in the previous office action teaches pushing the guide tube off the shaft. As such the previous rejection of the method claims with respect to Browning and Makower is sustained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-13, and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Giesy et al. (US 5334185).

Regarding Claim 1, Giesy teaches delivery device for delivering an implant to anatomical site in a body of a patient, the device comprising; a handle (12), a shaft having proximal and distal ends (20) and attached to the handle at the proximal end (20a), a pusher tube (22) slidably fitted over the shaft and extending from the handle distally along a portion of the shaft, and a pushing mechanism (24) operatively interconnected with the handle for actuating the pusher tube distally along a portion of the shaft to deliver an implant (40) to an anatomical site.

Regarding Claim 2, Giesy teaches the delivery device of claim 1, wherein the pusher tube (22) and the pushing mechanism (24) are integrated into a single assembly.

Regarding Claim 3, Giesy teaches the delivery device of claim 1, wherein the handle (12) includes a first axially extending recess (14) and the pushing mechanism includes a first axially extending tongue (25) for slidably interfitting with the first axially extending recess (30).

Regarding claim 4, Giesy teaches the delivery device of claim 3, wherein the handle includes a first stop (14a) located at a proximal end of the first axially extending recess (14) and the first axially extending tongue includes a projection (24) located at a distal end for engaging with the first stop to limit axial motion in a distal direction of the first tongue relative to the handle.

Regarding Claim 7, Giesy teaches the delivery device of claim 3, wherein the first axially extending tongue includes a first projection (24) located at a distal end for engaging with a proximal end (14a) of the first axially extending recess to limit axial motion in a proximal direction of the first tongue relative to the handle.

Regarding Claim 8, Giesy teaches the delivery system of claim 1, wherein the pushing mechanism (24) slidably interfits (25) over the shaft (20) and includes a pusher button (24) for actuating the pushing mechanism.

Regarding Claim 9, Giesy teaches the delivery system of claim 1, wherein the pusher button (24) includes a reduced diameter portion for accommodating a finger of a medical operator (upper portion of button 24 tapers).

Regarding Claim 10, Giesy teaches delivery device for delivering an implant to anatomical site in a body of a patient, the device comprising, an implant for being delivered to an anatomical site in the body of a patient, and a delivery device including, a handle (12), a shaft having proximal and distal ends

(20) and attached to the handle at the proximal end (20a), a pusher tube (22) slidably fitted over the shaft and extending from the handle distally along a portion of the shaft, and a pushing mechanism (24) operatively interconnected with the handle for actuating the pusher tube distally along a portion of the shaft to deliver an implant (40) to an anatomical site.

Regarding Claim 11, Giesy teaches the delivery device of claim 10, wherein the pusher tube (22) and the pushing mechanism (24) are integrated into a single assembly.

Regarding Claim 12, Giesy teaches the delivery device of claim 10, wherein the handle (12) includes a first axially extending recess (14) and the pushing mechanism includes a first axially extending tongue (25) for slidably interfitting with the first axially extending recess (30).

Regarding claim 13, Giesy teaches the delivery device of claim 12, wherein the handle includes a first stop (14a) located at a proximal end of the first axially extending recess (14) and the first axially extending tongue includes a projection (24) located at a distal end for engaging with the first stop to limit axial motion in a distal direction of the first tongue relative to the handle.

Regarding Claim 16, Giesy teaches the delivery device of claim 12, wherein the first axially extending tongue includes a first projection (24) located at a distal end for engaging with a proximal end (14a) of the first axially extending recess to limit axial motion in a proximal direction of the first tongue relative to the handle.

Regarding Claim 17, Giesy teaches the delivery system of claim 10, wherein the pushing mechanism (24) slidably interfits (25) over the shaft (20) and includes a pusher button (24) for actuating the pushing mechanism.

Regarding Claim 18, Giesy teaches the delivery system of claim 10, wherein the pusher button (24) includes a reduced diameter portion for accommodating a finger of a medical operator (upper portion of button 24 tapers).

Regarding Claim 19, Giesy teaches the delivery system of claim 10, wherein the implant comprises a sling (40) assembly having first (40a) and second (40b) ends.

Claims 10 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonutti (US ~~5841072~~ 5814072).

Regarding Claim 10, Bonutti teaches delivery device for delivering an implant to anatomical site in a body of a patient, the device comprising, an implant (30) for being delivered to an anatomical site in the body of a patient, and a delivery device including, a handle (22), a shaft having proximal and distal ends (92) and attached to the handle at the proximal end, a pusher tube (24) slidably fitted over the shaft and extending from the handle distally along a portion of the shaft, and a pushing mechanism (110) operatively interconnected with the handle for actuating the pusher tube distally along a portion of the shaft to deliver an implant (30) to an anatomical site.

Regarding Claim 19, Bonutti teaches the delivery system of claim 10, wherein the implant comprises a sling assembly (30, 32) having first and second ends.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 6, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy as a matter of design choice. Giesy teaches all limitations of preceding dependent claims 1, 3, 4, 10, 12 and 13 as previously described but fails to disclose wherein the handle includes a second axially extending recess substantially parallel to the first axially extending recess, and the pushing mechanism includes a second axially extending tongue for slidably interfitting with the second axially extending recess and a second stop associated therewith. Giesy discloses a first set of recess, tongue and stop for the purpose

of actuating the slidable tube. Since the applicant has not disclosed that adding a second set of actuating parts solves any stated purpose, and it appears that a single set of actuating parts as disclosed by Giesy would perform equally well as if a second set of actuating parts were present. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Giesy with a second set of actuation parts since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Cc v. Bemis Co., 193 USPQ 8.

Claims 20-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (US 6960160) in view of Makower et al. (US 5324306).

Browning teaches the following:

- an implant (10) for being delivered to an anatomical site in the body of a patient
- delivery device (50) including, a handle (52), a shaft (54) having proximal and distal ends and attached to the handle at the proximal end (fig. 15)
- an implant comprising a sling assembly (20) having first and second ends
- sling assembly includes a first guide tube (30) attached to the first end and a second guide tube (30) attached to the second end, and each of the first and second guide tubes are sized for slidably interftting over a distal end of the shaft (50)

- shaft (50) has a conical tip (fig. 8c) at the distal end and at least one end of the first and second guide tubes is tapered (upper portion in fig. 8a) to accommodate the conical tip.
- first and second guide tubes (30) are sized for interfitting, alternately, and one at a time, over the shaft (50) and abutting a distal end of the pusher tube (fig. 4).
- first guide tube (30) has proximal and distal ends and attaches at the proximal end to the first end of the sling assembly and slidably interfits over the shaft, proximal end first.

Browning fails to disclose a pusher tube slidably fitted over the shaft and extending from the handle distally along a portion of the shaft, and a pushing mechanism operatively interconnected with the handle for actuating the pusher tube distally along a portion of the shaft to deliver an implant to an anatomical site.

Makower teaches an implant introducer comprising a pusher tube (58) slidably fitted over the shaft (18) and extending from the handle (26) distally along a portion of the shaft, and a pushing mechanism (48) operatively interconnected with the handle (26) for actuating the pusher tube (58) distally along a portion of the shaft to deliver an implant (44) to an anatomical site in order to effectively eject the implant off of the shaft. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Browning with the pusher assembly of Makower in order to effectively eject the implant off of the shaft.

Regarding the limitation wherein the sling assembly is located at the proximal end of the guide tube, Browning teaches the device wherein the sling assembly is located at the distal end of the guide tube. It appears that the device of Browning performs the task of placing the sling equally well as that of the application wherein the sling is located at the proximal end of the guide tube. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Browning with the sling attached to the proximal end of the guide tube, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Regarding the method claims, the combination of Browning and Makower teaches the following:

- slidably interfitting a first guide tube attached to a first end of an implant over a distal end and along at least a portion of a length of a shaft (Browning Column 2, proximate lines 60-65), positioning at least the distal end of the shaft in a body of a patient (Browning Column 6, proximate lines 36-45), sliding the first guide tube off the shaft to deliver a first portion of the implant into the body of the patient (Browning fig. 8), slidably interfitting a second guide tube attached to a second end of the implant over the distal end and along at least a portion of the length of the shaft, positioning at least the distal end of the shaft in the body of the patient, and sliding the second guide tube of the shaft to deliver a second portion of the implant into the body of the patient (Browning Column 19-28).

- wherein the implant includes a sling (10) for treating urinary incontinence (Browning Column 1, proximate lines 4-10).
- using a pushing mechanism to slide the first and second guide tubes off the shaft (Makower Column 6, proximate lines 44-55).
- the first and second guide tubes have proximal and distal ends, attach at their respective proximal ends to the sling assembly, and the method comprises sliding the first and second guide tubes, proximal end first, over the distal end of the shaft (Browning fig. 9).
- delivering the implant to a mid-urethral position in the body of the patient (Browning Column 1, proximate lines 17-24).
- positioning the distal end of the shaft in the body of the patient inravaginally (Browning fig. 11).
- positioning steps for the first and second shafts are preformed before the sliding steps for the first and second steps (Browning figs. 8a-c).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
8/7/06

GLENN K. DAWSON
PRIMARY EXAMINER